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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/800,984	MULYE, NIRMAL	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 August 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38,40-48,54-56,59,60 and 63-73* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38,40-48,54-56,59,60 and 63-73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 20, 2010 has been entered.

2. Applicants' arguments, filed August 20, 2010, have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112 – 2nd Paragraph

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 38, 40 – 48, 54 – 56, 59, 60 and 63 – 73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For the

weight ratio of cellulose to maltodextrin, it is unclear if only the water insoluble or partially water soluble cellulose amounts is included in this calculation or if the total weight of all celluloses present in the composition are included. The sustained release carrier can be a cellulose as in claim 42 and it is unclear if the amount of cellulose would be included when the weight ratio of claim 38 is calculated. Also, claims such as claism 54 - 56 refrence the sum of the maltodextrin and cellulose it is similarly unclear if all cellulose ingreidnets are included in the sum or if only the water insoluble or partially water soluble cellulose is included in this sum. The rest of the claims fall therewith. Please clarify.

5. Claim 40 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 40 recites the limitation "the sustained release polymer" in line 2. There is insufficient antecedent basis for this limitation in the claim as claim 38 uses the phrase “sustained release carrier”.

6. Claim 59 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 59 recites the limitation "the solid unit dosage oral form" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 38, 43, 44, 46, 47, 54, 55, 59, 60, 63 – 65 and 71 – 73 were rejected under 35 U.S.C. 102(b) as being anticipated by Shah et al. (US 6,126,969). This rejection is MAINTAINED.

Shah et al. discloses the mixture of sustained release and uncoated acetaminophen compressed into tablets (col 8, ln 10 – 43) with formulations as set forth in Tables 1 and 2 (bridging cols 8 and 9). In the formulation set forth in Table 1, the uncoated tablet contains a pharmaceutically effective amount of acetaminophen, a sustained release carrier of isononylphenyl polyoxyethylene glycol ethers and methacrylate ester copolymers, 0.449% of the lubricant magnesium stearate, less than 3.305% maltodextrin and 6.856% microcrystalline cellulose (MCC). The ratio of water insoluble or partially water insoluble cellulose (MCC) to maltodextrin is 1:2.1, assuming 3.305% maltodextrin is present. In this composition, the MCC and maltodextrin are about 10% by weight of the core formulation.

Applicant traverses this rejection on the grounds that the present invention requires interaction of maltodextrin with the water insoluble or partially water soluble

cellulose and the interaction of both with the sustained release polymer and drug. Thus, all four components need to be present in the core. The formulation of example 1 of Shah et al. has microcrystalline cellulose and sustained release coated acetaminophen while the maltodextrin is present in a different layer with the immediate release acetaminophen. Unlike in the present invention, the maltodextrin cannot interact with the microcrystalline cellulose. These arguments are unpersuasive. The instant claims do not require the interaction of all 4 of these ingredients – only that these ingredients are present in the core of the oral pharmaceutical composition. Contrary to Applicants assertion, the sustained and immediate release acetaminophen are not present in layers but are mixed together ("the mixture of coated acetaminophen and micro-crystalline cellulose are then preferably combined with the uncoated acetaminophen" that is mixed with magnesium stearate and then compressed into a caplet (col 8, ln 20 - 34) so the core is mixture of the listed required ingredients.

9. Claims 38, 43, 54 – 56, 59, 60 and 71 – 73 were rejected under 35 U.S.C. 102(b) as being anticipated by Seroff et al. (US 6,387,403). This rejection is MAINTAINED.

Seroff et al. discloses a dosage form with an internal compartment comprising a bilayered compressed core with a drug layer and a push layer (components 16 and 17 respectively in figure 2). In Example 4B (col 22, ln 24 – 50), the drug layer comprises a pharmaceutically acceptable amount of reboxeinate methanesulfonate, maltodextrin and stearic acid, a lubricant. The push layer comprises polyethylene oxide, which reads on a hydrophilic polymer that is sustained release carrier (see claim 71 of the instant

application), hydropropyl methyl cellulose 2910 (HPMC) and magnesium stearate, a lubricant. The ratio of cellulose to maltodextrin in this composition is 1:28. Based on the total weight of the composition, the composition comprises approximately 38% maltodextrin and 1.4% HPMC. The ranges recited for the total amount of cellulose and maltodextrin present in the composition are expanded beyond the numerical values recited because of the use of the word "about" and therefore the amounts present in the compositions of Seroff et al. anticipate the claims of the instant application.

Applicant traverses this rejection on the grounds that Seroff does not arrange the elements as in the claims because the cellulose ether and maltodextrin are contained in different layers. The maltodextrin is not part of the sustained release formulation. The drug, the cellulose, maltodextrin and sustained release polymer are not present in the core as claimed. These arguments are unpersuasive. The claim only requires that the listed ingredients are present in the core and applicants have not defined the core as, for example, having a homogenous composition throughout. Thus, "core" as used in the instant claims does not exclude the bilayer tablet core of Seroff and Seroff anticipates the instant claims.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

> invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 38, 43, 44, 46, 47, 54 – 56, 59, 60, 63 – 66 and 71 – 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shah et al. (US 6,126,969). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed July 21, 2009 reiterated below and the reasons set forth below.

Shah et al. discloses the mixture of sustained release and uncoated acetaminophen compressed into tablets (col 8, ln 10 – 43) with formulations as set forth in Tables 1 and 2 (bridging cols 8 and 9). In the formulation set forth in Table 1, the uncoated tablet contains a pharmaceutically effective amount of acetaminophen, a sustained release carrier of isononylphenyl polyoxyethylene glycol ethers and methacrylate ester copolymers, 0.449% of the lubricant magnesium stearate, less than 3.305% maltodextrin and 6.856% microcrystalline cellulose (MCC). The ratio of water insoluble or partially water insoluble cellulose (MCC) to maltodextrin is 1:2.1, assuming 3.305% maltodextrin is present. In this composition, the MCC and maltodextrin are about 10% by weight of the core formulation.

Shah et al. does not explicitly disclose formulations that contains between 20% to 50% of cellulose and maltodextrin.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to alter the amount of ingredients such as HPMC present in the composition. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because HPMC is well-known and commonly used pharmaceutical excipient that acts a binder to impart cohesive properties to powdered material (see US 6,248,363, col 39, ln 31 – 37). The amount of a specific ingredient such as MCC or maltodextrin in a composition is thus a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results of the sustained release properties and the physical properties of the ingredients used to form the core (e.g., flowability, compressibility) and the resulting final tablet core.

Applicants traverse this rejection on the same grounds discussed above regarding this reference applied under 35 USC 102(b). As discussed in greater detail above, the instant claims do not require interaction of all the listed ingredients with each other but rather that they are present in the core of the tablet. The formulations of Shah meet those limitations so this rejection is maintained.

13. Claims 38, 40 - 44, 46 - 48, 54 – 56, 59, 60 and 63 – 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shah et al. as applied to claims 38, 43, 44, 46, 47, 54 – 56, 59, 60, 63 – 66 and 71 – 73 above, and further in view of Mulye et al. (US 6,416,786). This rejection is MAINTAINED.

Shah et al. discloses compositions with a core comprising a mixture of drug (acetaminophen), maltodextrin, magnesium stearate and MCC.

Shah et al. does not disclose xanthan gum in conjunction with a cellulose ether as the sustained release material or the use of silicified MCC (SMCC).

Mulye et al. discloses a solid sustained release tablet comprising a hydrocolloid such as xanthan gum and a cellulose ether as the sustained release carrier (abstract). A variety of active ingredients can be included in the sustained release formulation (col 3, ln 65 – col 4, ln 25). The amount of hydrocolloid and cellulose ether present are preferably between about 1:0.01 to about 1:2, or more preferably 1:0.05 to about 1:0.4 (col 6, ln 37 – 41). Hydroxypropylmethylcellulose in various forms are disclosed as suitable for the cellulose ether fraction of the sustained release carrier (col 4, ln 44 – 67). A filler such as the pharmaceutically acceptable saccharide microcrystalline cellulose can also be included (col 7, ln 3 – 17). In example 1 (col 9, ln 57 – 63), niacin, xanthan gum (XG), HPMC, SMCC and talc are made into tablets. The ratio of XG:HPMC is 1:0.5. The other non-comparative examples make use of xanthan gum and HPMC with SMCC, although the ratio of XG:HPMC varies.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate a cellulose ether and xanthan gum sustained release

carrier into the formulations of Shah et al. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because Mulye et al. discloses that this combination of polymers is useful as a sustained release carrier. The different sustained release materials and combinations of materials will provide for different release profiles of the active ingredient. Based on the desired properties, one of ordinary skill in the art would select an appropriate sustained release carrier and other excipients that provides the desired release profile of the particular active ingredient present in the dosage form.

Applicants traverse this rejection on the grounds that Mulye does not cure the deficiency of Shah et al. These arguments are unpersuasive. As discussed in greater detail above, Shah et al. is not deficient as alleged by Applicant so the rejection is maintained for the reasons of record.

14. Claims 38, 43, 44, 46 - 48, 54 – 56, 59, 60 and 63 – 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shah et al. as applied to claims 38, 43, 44, 46, 47, 54 – 56, 59, 60, 63 – 66 and 71 – 73 above, and further in view of Tobyn et al. (Intl J Pharm 1998). This rejection is MAINTAINED.

Shah et al. discloses compositions with a core comprising a mixture of drug (acetaminophen), maltodextrin, magnesium stearate and MCC.

Shah et al. does not disclose the use of silicified microcrystalline cellulose (SMCC).

Tobyn et al. discloses the MCC is widely used as a filler and binder for wet granulation, direct compression tabletting and as a filler for hard gelatin capsules (p 183, col 1, ¶1) and it has been rated as the most useful filler for direct compression tabletting (p 183, col 2, ¶1). While MCC is very useful, SMCC possesses a number of advantages in terms of powder flow, tablet strength, lubricant sensitivity and wet granulation (p 184, col 2, ¶ 1).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate SMCC into the composition of Shah et al. that comprises drug, maltodextrin, magnesium stearate, MCC and HPMC. The person of ordinary skill in the art would have been motivated to make those modifications, because and reasonably would have expected success because Tobyn et al discloses that SMCC is useful in the tabletting process with improved properties over non-silicified MCC used in Shah et al.

Applicants traverse this rejection on the grounds that Tobyn does not cure the deficiency of Shah et al. These arguments are unpersuasive. As discussed in greater detail above, Shah et al. is not deficient as alleged by Applicant so the rejection is maintained for the reasons of record.

15. Claims 38, 43 - 47, 54 – 56, 59, 60, 63 – 66 and 71 – 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shah et al. as applied to claims 38, 43, 44, 46, 47, 54 – 56, 59, 60, 63 – 66 and 71 – 73 above, and further in view of Shell et al. (US 6,340,475). This rejection is MAINTAINED.

Shah et al. discloses compositions with a core comprising a mixture of drug (acetaminophen), maltodextrin, magnesium stearate and MCC.

Shah et al. does not disclose metformin as an active ingredient which can be included in the formulation.

Shell et al. discloses controlled release formulations that release the drugs, such as highly soluble drugs, over extended periods of time which provide a number of improvements verses non–controlled release formulations (col 1, ln 12 – 43). Among the drugs that are highly water soluble which would benefit from being released in a controlled manner is metformin hydrochloride (col 7, ln 39 – 41).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to prepare a dosage form comprising active ingredient, MCC, maltodextrin and lubricant as taught by Shah et al. and to incorporate metformin as the active pharmaceutical ingredient. The person of ordinary skill in the art would have been motivated to make those modifications in order to prepare a controlled release dosage form of metformin to administer to diabetic individuals and reasonably would have expected success because Shah et al. teaches that the compositions can be used generally for the delivery of pharmaceutical agents other than the exemplified acetaminophen (col 2, ln 47 – 54).

Applicants traverse this rejection on the grounds that Shell does not cure the deficiency of Shah et al. These arguments are unpersuasive. As discussed in greater detail above, Shah et al. is not deficient as alleged by Applicant so the rejection is maintained for the reasons of record.

16. Claims 38, 40 – 47, 54 – 56, 59, 60, 63 – 66 and 71 – 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seroff et al. (US 6,387,403) in view of Shell et al. (US 6,340,475). This rejection is MAINTAINED.

Seroff et al. discloses a dosage form with an internal compartment comprising a bilayered compressed core with a drug layer and a push layer (components 16 and 17 respectively in figure 2). In Example 4B (col 22, ln 24 – 50), the drug layer comprises a pharmaceutically acceptable amount of reboxeinate methanesulfonate, maltodextrin and stearic acid, a lubricant. The push layer comprises polyethylene oxide, which reads on a hydrophilic polymer that is sustained release carrier (see claim 71 of the instant application), hydroxypropyl methyl cellulose 2910 (HPMC) and magnesium stearate, a lubricant. The ratio of cellulose to maltodextrin in this composition is 1:28. Based on the total weight of the composition, the composition comprises approximately 38% maltodextrin and 1.4% HPMC.

Seroff et al. does not disclose the drug metformin or the use of a combination of cellulose ether and xanthan gum, microcrystalline cellulose.

Shell et al. discloses compositions wherein drug release is accomplished by the imbibition of water by hydrophilic polymers (abstract). The water-swellable polymers can be made from a variety of materials, including a variety of celluloses, including microcrystalline cellulose (col 7, ln 62), hydroxymethyl-cellulose, hydroxyethyl cellulose, HPMC and carboxymethyl cellulose (col 8, ln 15 – 17). The polymers can be used individually or in combination as certain combinations will often provide a more

controlled release of drug than the components when used individually, such as cellulose-based polymers with gums (col 9, ln 42 – 48). For example, in example 6 the samples represented by open triangles are a combination of hydroxyethylcellulose (a cellulose ether) and xanthan gum (1:1 ratio; col 15, ln 16 – 21). Both hydroxy ethylcellulose and HPMC are particularly preferred as the cellulose polymer (col 8, ln 23 – 25). Among the drugs that are highly water soluble which would benefit from being released in a controlled manner is metformin hydrochloride (col 7, ln 39 – 41).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate the water-imbibing polymers and combinations of polymers as the push layer of the pharmaceutical dosage forms of Seroff et al. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success as the push layer of Seroff et al. and water-soluble polymers that imbibe water in the dosage form of Shell et al. are the same and actuate drug release in the same manner. Shell et al. discloses that a combination of polymers can provide better controlled release than the individual components. Thus one of ordinary skill in the art would select water-soluble polymers and/or combinations of water soluble polymers, such either hydroxyethylcellullose or HPMC with xanthan gum, that provide an appropriate rate of swelling and thus control release of the active ingredient. The polymers used and the amount of these ingredients are results effective parameters that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It

would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results or rlease rate and release duration.

Shell et al. also teaches metformin as one active ingredient that can be released in a controlled fashion to provide a variety of benefits. Thus one of ordinary skill in the art would prepare a controlled dosage form with metformin as the active ingredient.

Applicants traverse this rejection on the same grounds discussed above regarding Seroff applied under 35 USC 102(b). As discussed in greater detail above, the instant claims do not exclude a bilayered core or a heterogeneous core require interaction of all the listed ingredients with each other but rather that the listed ingredients are present in the core of the tablet. The formulations of Seroff meet those limitations so this rejection is maintained.

17. Claims 38, 40 – 48, 54 – 56, 59, 60 and 63 – 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seroff et al. and Shell et al. as applied to claims 38, 40 – 47, 54 – 56, 59, 60, 63 – 66 and 71 – 73 above, and further in view of Tobyn et al. (Intl J Pharm 1998). This rejection is MAINTAINED.

Seroff et al. and Shell et al. disclose compositions comprising water-swellable polymers, such as HEC, HPMC and poly(alkylene oxides) alone or in combination with gums such as xanthan gum. The selection of the polymers and the amounts of those polymers will control the rate of water-swelling and thus the release rate of the drug.

The compositions provide for the controlled release of active ingredients like metformin over time.

Shah et al. does not disclose the use of silicified microcrystalline cellulose (SMCC).

Tobyn et al. discloses the MCC is widely used as a filler and binder for wet granulation, direct compression tabletting and a filler for hard gelatin capsules (p 183, col 1, ¶1) and it has been rated as the most useful filler for direct compression tabletting (p 183, col 2, ¶1). While MCC is very useful, SMCC possesses a number of advantages in terms of powder flow, tablet strength, lubricant sensitivity and wet granulation (p 184, col 2, ¶ 1).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate SMCC in place of MCC into the formulations of Seroff et al. and Shah et al. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because Tobyn et al. teaches the improved behavior of SMCC when formulations are prepared.

Applicants traverse this rejection on the grounds that Tobyn does not cure the deficiency of Seroff et al. and Shell et al. These arguments are unpersuasive. As discussed in greater detail above, Seroff et al. and Shell et al. are not deficient as alleged by Applicant so the rejection is maintained for the reasons of record.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nissa M Westerberg/
Examiner, Art Unit 1618